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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,481	07/18/2003	Jong Lim	66631.8013	4558

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
02/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,481	LIM ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 11/09/09

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosure of Johnson et al (USPN 6,171,618 hereafter '618).

5. The '618 patent is drawn to a method of making a combination dosage form comprising two separate drugs having different release rates (abstract). The first drug (the controlled release agent) is released so that at least 75% of the drug is released over a period of 4-36 hours (col. 3, lin. 10-15). The first drug is formed into a core with a solid matrix material such as microcrystalline cellulose and hydroxypropyl cellulose (col. 17, lin. 50-55). The drug material is dispersed in the solid matrix (col. 6, lin. 57-65). The core is then coated with a solution of a polymer matrix not comprising a drug and can fully encompass the core or cover sections having pores (col. 18, lin. 5-10; col. 10, lin. 8-68). The pores measure less than 50 microns, meaning the drugs must measure far below 50 microns (col. 10, lin. 55-60). The pores form after administration and as such do not allow for interaction between the coating layer drugs and the drugs of the matrix core. The polymer matrix comprises polyvinyl alcohol (col. 9, lin. 25). The resultant coated core is further coated with a drug formulation (col. 18, lin. 30-40). The tablets are dried leaving a solid two drug controlled release agent with the top drug formulation releases immediately while the inner coated drug releases slower (examples). Solvents include water, ethanol and acetone (example). The weight ratio of the polymeric film to the unitary body (core) is approximately 0.16:1 (example 2).

6. The reference differs from the instant claims in disclosures of the ratio of unitary dosage from to the polymeric film, however this limitation is well within the limits of one of ordinary skill in the art to manipulate and arrive at through routine experimentation.

The reference is further silent to the specific amount of first drug is release within the first hour. Although 75% of the drug is release over a period of 4-36 hours, there are no explicit disclosures for the first hour. However it is the position of the Examiner that this release rate like many properties can be manipulated and derived from routine experimentation. As discussed above the ratio of polymeric film to unitary dosage overlaps the range of the instant claims (0.16:1). It is the position of the Examiner that these specific ratios represent an optimized result determined through routine experimentation and do not impart patentability on the claims.

7. With the things in mind it would have been obvious to one of ordinary skill in the art to follow the suggestions of the art to follow the teachings and suggestions of the art in order to provide a stable combination therapy useful in treating various disorders. One of ordinary skill in the art would have been motivated to follow these teachings with an expected result of a combination therapy useful in treating various disorders.

Response to Arguments

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that:

a. The ‘618 patent does not disclose all the limitations of the instant claims.

b. Any modifications to the '618 would not render the formulation inoperable and not result in the instant invention.

Regarding argument a., it remains the position of the Examiner that the ‘618 patent continues to obviate the instant claims. Applicant argues that the membrane applied tot he matrix cores disclosed in the '618 patent would not dissolve in gastrointestinal fluid as required by the 9instant claims. Applicant argues that although polyvinyl alcohol is recited in the instant claims and disclosed in the ‘618 patent as useful components to the membrane that covers the unitary body, the polyvinyl alcohol of the instant claims must be of a different “molecular weight, degree of cross-linking, etc” in order to dissolve as required by the instant claims. Applicant argues that the membrane of the ‘618 patent does not dissolve in the gastrointestinal tract. The Examiner respectfully disagrees with these arguments.

First the claims require dissolution of the membrane yet is silent to the amount of dissolution. The '618 patent clearly discloses that portions of the membrane completely dissolve upon exposure to gastrointestinal fluid, creating pores (col. 10, lin. 35-50). Second polyvinyl alcohol is recited in the instant claims as a membrane polymer and disclosed by the '618 patent as a membrane polymer that would dissolve in the gastrointestinal tract. Applicant speculates that there must be a difference between the identically named and identified polymers, yet provides no evidence to support such a difference. True, molecular weight, cross-linking, etc., can change a polymer’s properties, yet none of these propertie4s have been claimed or recited anywhere in the instant claims or specification. Applicant is arguing speculated elements of the instant invention which are not present in the instant claims. Third, though the membrane of the ‘618 is disclosed an impermeable, the term is defined by the patent as to mean

impermeable to psuedoephedrine, which eliminates drug interaction between the sustained and instant release components before release. The drug-free membrane surrounding the sustained release second drug unitary body comprises leachable materials such as polyvinyl alcohol and semi-permeable materials such as cellulose acetate. These components would form a film that dissolves in gastrointestinal fluid. As such it remains the position of the Examiner that the '618 patent discloses a method of manufacture where a drug is dispersed in a matrix (col. 6, lin. 57-65) and forms a solid unitary body, that body is coated with a drug-free polymeric coating that would dissolve in gastrointestinal fluid at least partially, and does not allow for drug interaction (col. 8, lin. 50-55; col. 9, lin. 25-col. 10, lin. 55). Next the coated unitary body has another drug deposited on its surface where the drug is in a fluid medium (Example 1), whereby the fluid medium is driven off leaving a solid unitary body (Example 2). For these reasons the claims remain obviated.

Regarding argument b., it remains the position of the Examiner that the '618 patent continues to obviate the instant claims. The only modifications proposed by the Examiner are those to optimize the ratios of the polymeric film to the unitary body, and the release rate of the first and second drug, which can be arrive upon through routine experimentation. The modifications Applicant proposes appear to be unnecessary to meet the limitations of the instant claims. The claims require that the drug free membrane dissolve, yet do not recite how much dissolution must occur. As such any amount of dissolution would meet this limitation. The semi-permeable polymer film composition of the '618 patent would some what dissolve meeting the limitations of the

instant claims. Applicant argues that the function of the instant invention differs from the '618 patent, since the sustained release core can function without a rate limiting film. This function is not however claimed. Again Applicant attempts to argue aspects of the invention that are not presently claimed. The limitations that *have* been claimed, as discussed above have been met by the '618 patent. For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on M-F 8-5:30, First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Micah-Paul Young/
Examiner, Art Unit 1618